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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David Hung

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CYTYC CORPORATION

250 CAMPUS DRIVE

MARLBOROUGH, MA 01752

EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/827,371

Applicant(s)

HUNG, DAVID

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6 and 22-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on November 19, 2006.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

The originally elected species was not found; therefore the claims were examined on the merits until the next species of the claim was found.

**Claims 1, 6 and 22-27 are under examination.**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 7 and 22-27, as amended, remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising intraductally to the patient an effective of mannitol that increases the ductal fluid collection from a breast duct of a patient, does not reasonably provide enablement

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for the claim-designated method comprising the intraductal administration of any and all amounts of any and all of the agents recited in the Markush group of Claim 1. The specification does not enable any person skilled in the art to which it pertains, or with it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as broadly claimed by Applicant.

Applicant's main argument is directed to the idea that one of ordinary skill in the art would be able to make and use the entire scope of the claimed invention without undue experimentation. Applicant further argues that a claim can encompass "inoperative" embodiments so long as one of ordinary skill in the art can ascertain this without undue experimentation. Because the Examiner indicates that the specification is enabled for a method for intraductal retrieval of fluid, cells and/or other material from a breast duct of patient comprising administering an effective amount of mannitol that increases the ductal fluid collection from a breast of a patient, Applicant argues that one of skill in the art could easily conclude that the administration of high molecular weight hygroscopic agents into a breast would potentially increase the amount of ductal fluid within the breast duct. Applicant further argues that the specification discloses the experimental protocol for the administration of agents to a breast duct. Thereby, Applicant concludes that one of skill in the art would easily know to introduce hydroscopic agents into the breast of a patient to (or an animal model) to test for an increase in intraductal fluid. Finally, Applicant argues, "Hence, inoperative embodiments encompassed by claim 1 (i.e., agents that are non-hygroscopic) could be easily identified by one of skill in the art without undue experimentation.

Each of Applicant's arguments have been fully considered but are found neither persuasive nor commensurate in scope to the claims because enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. All of the *Wands* factors have been considered with regard to the instant claims to create a *prima facie* case, with the most relevant factors discussed below. Therefore, the rejection remains for the reasons set forth in the previous Office action and for all of the reasons set forth herein. Please note that the Examiner has slightly modified the format of the previous rejection so that Applicant may fully understand all of the Wands factors set forth below and fully understand why the rejection was maintained.

*Nature of the Invention.* The claims are drawn to a method to a method for increasing retrievable intraductal fluid, cells and/or other material from a breast duct of a patient comprising administering to the patient an agent that increases the secretion of ductal fluid into a breast duct, wherein the agent is selected from the group consisting of a hypotonic solution, a buffered solution, a buffered solution, a nonabsorbable compatible solution, a protein, a colloid, a sugar, a polymer, mannitol, sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose, polyethyleneglycol (PEG), maltodextrin,

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dextran 70, hydroxyethyl starch, fluid gelatin, a synthetic colloid, an antibody, a binding protein, albumin, a hormone, a natural herb, an extract from a natural herb, silymarin, a surfactant, a growth factor, oxytocin, prolactin, an organic molecule, a muscle relaxant, and a ductal orifice dilator.

*Breadth of the Claims.* The claims are broad in that any and all amounts of the claim-designated agents as recited in the Markush of group Claim 1 are intraductally administered to a patient to provide a method for increasing retrievable intraductal fluid, cells and/or other material from a breast duct of a patient, wherein the intraductal administration of the claim-designated agents increases secretion of ductal fluid into a breast duct. The complex nature of the subject matter of the invention is clearly exacerbated by the breadth of the claims.

*Guidance of the Specification and Existence of Working Examples.* While Applicant has reasonably demonstrated a method for increasing retrievable intraductal fluid, cells and/or other material from a breast duct of a patient comprising the intraductal administration of effective amount of mannitol that increases the amount of ductal fluid in the breast duct, Applicant has not demonstrated a method for increasing retrievable fluid, cells and/or other material from a breast duct of a patient comprising the intraductal administration of any and all of the agents recited in the Markush group of Claim 1 in any and all amounts to provide the claim-designated functional effect to increase secretion of ductal fluid into a breast duct of a patient. For instance, on page 14 of the specification, line 20 to page 16, Applicant exemplifies a method of intraductally administering an effective amount of mannitol in water to the breast of a

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rabbit to provide a method the claim-designated functional effect to increase ductal fluid secretion. However, Applicant has not demonstrated a method for increasing retrieval intraductal fluid, cells and/or other material from a breast of a patient comprising the intraductal administration of any and all of the claim-designated agents in any and all amounts, wherein the intraductal administration of any and all of the claim-designated agents in any and all amounts increase secretion of ductal fluid into the breast of a patient as broadly claimed by Applicant.

*Predictability and State of the Art.* While it may possible that particular agents recited in the Markush group of Claim 1 would increase the secretion of ductal fluid into a breast duct of a patient, it is highly unlikely that any and all of the claim-designated agents in any and all amounts could increase secretion of ductal fluid into a breast duct. The Office notes that on page 5, lines 20-24, Applicant expressly states, "The invention is the discovery that by first artificially increasing the fluid volume or fluid reservoir in a breast duct and breast." On page 8 of the specification, lines 3-24, it appears that Applicant discloses that the intraductal administration of some the claim-designated agents may not indeed increase secretion of ductal fluid but rather increase or at least maintain the amount of collectable fluid already present in the lumen of the breast duct. It should be noted that the state of the art at the time the invention was made did not recognize that all of the instantly claimed agents could increase the secretion of ductal fluid into the breast of a duct. For instance, Nikodem et al. (W, Birth, 1993, 20:61-64. *Do cabbage leaves prevent breast engorgement?*) teach that cabbage leaf extract discourages the secretion of fluid into the breast duct of a patient.

*Amount of Experimentation Necessary.* There is no guidance in the specification, other than the administration of effective amounts of mannitol to increase ductal fluid secretion from a breast duct. Moreover, the instant application does not provide a working example providing data which shows that the compositions of the instant claims would indeed increase secretion of fluid into a breast duct of a patient comprising the administration of any and all of the claim-designated agents in any and all amounts. Thus, Applicant has not demonstrated that any and all of the claim-designated agents have the claimed functional effect of increasing secretion of ductal fluid into a breast duct of a patient when intraductally administered to provide the instantly claimed method as broadly claimed, other than the aforementioned intraductal administration of effective amounts of mannitol. Accordingly, it would take undue experimentation without a reasonable expectation of success for one skill in the art to make and/or use the method as broadly claimed by Applicant.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to make and/or use the instantly claimed method. Contrary to Applicant's arguments, the quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to make and/or use the instantly claimed method comprising the intraductal administration of any and all of the claim-designated agents in any and all amounts to the breast duct of a patient to provide the functional effect of increasing secretion of ductal fluid into a breast duct.



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Therefore, all of the claims are not considered to be fully enabled by the instant specification.

Applicant argues that the Examiner has indicated enabling embodiments of the specification; and, therefore, one could easily conclude that the administration of high molecular weight hygroscopic agents would potentially increase the amount of ductal fluid within the breast duct of a patient. However, Applicant's argument is neither persuasive nor commensurate in scope to the limitations of the claimed invention because not all of the claim-designated agents recited in the Markush group of Claim 1 as well as dependent claims therefrom, are necessarily hygroscopic agents. Moreover, nowhere in the specification as originally filed does Applicant expressly suggest the intraductal administration of hygroscopic agents to the breast of a patient to provide the instantly claimed method of treatment. While Applicant argues "it must be remembered that a claim can encompass 'inoperative' embodiments so long as one of ordinary skill can ascertain this without undue experimentation, Applicant is directed to MPEP 2164.08(b) that states the following:

"Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable. A disclosure of a large number of operable embodiments and the identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable. In re Angstadt, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976). However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is

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involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971)."

In the instant case, the constituents recited in the Markush of Claim 1 are directed to a plethora of possible agents characterized by divergently different chemical constituents or by divergently different botanical extracts that have or possibly could have divergently different biological and/or biochemical functions other than increasing the secretion of ductal fluid into the breast duct of patient when intraductally introduced thereto. Applicant has identified a single operable embodiment but the claims read on significant numbers of possible inoperative embodiments and therefore the claims are rendered nonenbled because the specification as originally does not clearly identify the operative embodiments (other than the aforementioned enabled agent) and undue experimentation is involved in determining those that are operative. For example, Claim 1 and Claim 26 recite "a natural herb" and/or "an extract from a natural herb" as agents for use in the instantly claimed method. However, the only herbal extract recited in Claim 1 is "silymarin". The Office notes that at the time of filing the present invention, the state of the art of botany recognized numerous genera found in the various known plant families (which may comprise a plethora of subfamilies). Yet, the claims as drafted are rather broad in scope - - the broadness not being supported by the description with examples. For instance, D. J. Mabberley lists over 20,000 entries on every family and genus of seed-bearing plant, including gymnosperms plus ferns and other pteridophytes in *The Plant Book*, 2<sup>nd</sup> Edition, 1997. Cambridge University Press, The United Kingdom. Given that Applicant's invention is predicated upon the idea that

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the intraductal administration of a myriad of possible natural herbs or natural herbal extracts derived from a great number of plant families and genera thereof having various complex properties and compounds obtained therefrom, it would take undue experimentation without a reasonable expectation of success as how to identify and how to determine the source of the plant, the solvents used in the making of the plant extract, and how to determine the plant parts used in the making of an herbal extract, such that it would it have the functional effect to increase the secretion of ductal fluid into a breast duct of a patient when intraductally administered thereto, as instantly claimed by Applicant. The Office further notes that Claim 1 also recites a buffered solution as an agent for use in the instantly claimed method. However, by way of demonstration even Applicant readily discloses that the intraductal administration of phosphate buffered saline to the breast duct of a patient was not useful in the secretion of ductal fluid into the breast duct of the treated patient when administered in any and all amounts. See Table III on page 15.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art and lack of a sufficient number of working examples, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to make and/or use the instantly claimed method, as broadly claimed by Applicant.

***Claim Rejections - 35 USC § 102***

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Claim 1, as amended, and 22 remains/is rejected under 35 U.S.C. 102(b) as being anticipated by Love et al. (A\*). Applicant's arguments have been fully considered. However, the rejection remains for the reasons set forth below.

Applicant reasonably argues that physiological saline taught by Love is not an organic compound. However, the identification of the Love' agent was an obvious typographical error. Therefore, the Love anticipates the instantly claimed invention because Love teaches the intraductal administration of physiological saline to a breast duct for the retrieval of fluid, cells and/or other material from a breast of a patient. In Column 6, lines 55-67, Love discloses that "The volume of fluid introduced into the ductal network D<sub>2</sub> will be sufficiently large so that substantially the entire volume of the ductal network may be filled with the washing fluid and excess fluid will flow from the network as it is displaced by additional fluid input . . . The remaining fluid will continue to be introduced and will thus flush the cellular and other marker materials from the ductal network into the opening . . ." After collection of the washing fluid comprising the retrievable fluid obtained from the breast duct through a double lumen catheter, Love teaches analyzing the fluid to identify a marker of a breast condition (see Column 5, lines 38-44). Given the claims the broadest interpretation of the term "a nonabsorbable biocompatible solution", the Examiner regards the physiological saline washing fluid taught by Love as an "a nonabsorbable biocompatible solution".

The reference anticipates the claimed subject matter.

Claim 1, as amended, and Claims 6, 22, 25 and 27 is/remain rejected under 35 U.S.C. 102(b) as being anticipated by Martyn et al. (V), as evidenced by the teachings of Kartinos et al. (B\*) and Mullins (C\*). Applicant's arguments have been fully considered. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth below.

Contrary to Applicant's argument, Claim 1 does not recite "a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient that increases retrievable ductal fluid from a breast duct wherein the agent is selected from the constituents contained in the Markush group of Claim 1". Therefore, Applicant's argument is not commensurate in scope to the limitations of the instantly claimed invention; and, Applicant's argument is not persuasive because they are directed to limitations not entered. Next, Applicant argues, "The Examiner has limited Claim 1 to the species nonabsorbable biocompatible solution. Therefore, any reference cited by the Examiner must teach or suggest that a nonabsorbable biocompatible solution must be administered intraductally to a patient and the nonabsorbable biocompatible solution must cause an increase in the retrievable ductal fluid from a breast duct." Given that Claims 1, 6, 22, 25 and 27 were rejected under 35 U.S.C. 102(b) as being anticipated by Martyn, it is clear that the Examiner has not limited Claim 1 to the single species nonabsorbable biocompatible solution. Therefore, Applicant's argument is not persuasive because Martyn teaches a method increasing retrievable intraductal fluid, cells and/or other material from a breast duct of a patient comprising administering

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intraductally to the patient prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins). The emulsion was prepared by sonicating an aqueous solution phase consisting of phosphate buffer saline containing bovine serum albumin and Blue Dextran with safflower oil (see page 323, Column 2, under "*Mammary intraductal injections*"). In Table 1, Martyn shows that glycerolipid synthesis in the mammary gland was significantly enhanced in the presence of insulin, corticosterone and prolactin; addition of prolactin stimulated acetyl-CoA carboxylase activity; prolactin together with insulin and corticosterone stimulated activity of fatty acid synthetase; glucose-6-phosphate dehydrogenase was enhanced with prolactin injection. On page 326, Column 1, lines 9-27, Martyn teaches that intraductal injection of prolactin, or prolactin plus progesterone, had more secretion than did untreated emulsion treated or progesterone-treated glands within the same patient. It must be remembered that the entire teachings of a relied upon reference should be considered and not individual citations or sections contained therein the reference. The entirety of all of the teachings of a cited reference makes up the state of the art with regard to the claimed invention. Applicant's instantly claimed invention fails to patentably distinguish over the teachings of Martyn because Martyn teaches a method for increasing retrievable intraductal fluid, cells and/or other material from a breast duct of a patient comprising the intraductal administration of an nonabsorbable biocompatible solution or emulsion comprising

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prolactin or prolactin and progesterone, which increases secretion of ductal fluid into the breast duct.

The reference anticipates the claimed subject matter.

Claim 1, as amended, and Claims 6, 22, 25 and 27 is/remain rejected under 35 U.S.C. 102(b) as being anticipated by Falconer et al. (U), as evidenced by the teachings of Kartinos et al. (B) and Mullins (C). Applicant's arguments have been fully considered. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth below.

Contrary to Applicant's argument, Claim 1 does not recite "a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient that increases retrievable ductal fluid from a breast duct wherein the agent is selected from the constituents contained in the Markush group of Claim 1". Therefore, Applicant's argument is not commensurate in scope to the limitations of the instantly claimed invention; and, Applicant's argument is not persuasive because they are directed to limitations not entered. Therefore, the reference anticipates the claimed subject matter because, on page 182, Column 2, lines 6-15, Falconer teaches a method for increasing intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na<sup>+</sup>], [K<sup>+</sup>] and [Cl<sup>-</sup>] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution, as evidenced by the teachings of

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Kartinos and Mullins). Falconer further teaches removing and sampling alveolar tissue associated with the injected duct systems for water content determinations and Na<sup>+</sup>, K<sup>+</sup> and Cl<sup>-</sup> and [14C]-lactose analysis, on page 184, Column 2, lines 29-33. In Table 1, Falconer shows that increasing the amounts of prolactin increased the water content of wet tissue in the treated mammary gland tissue. On page 184, Column 1, lines 13-19 bridging Column 2, lines 1-6, Falconer teaches *in vivo* intraductal injection of prolactin to a patient showed an increase [K<sup>+</sup>] of 10 mmol/kg wet tissue (see Table 3); whereas, *in vivo* intraductal administration of prolactin and ouabain an increase [Na<sup>+</sup>]. On page 182, Column 2, lines 14-19, Falconer teaches an increased extracellular water content of the ouabain-treated glands (see Table 3). Table 3 also shows an increased extracellular water content of the prolactin-treated glands, as well.

The reference anticipates the claimed subject matter.

**No claims are allowed.**

\* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**MICHELE FLOOD**  
**PRIMARY EXAMINER**

Michele Flood  
Primary Examiner  
Art Unit 1655

MCF  
February 19, 2007